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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,187

09/25/2006

James Van Alstine

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09/30/2008

GE HEALTHCARE BIO-SCIENCES CORP.  
PATENT DEPARTMENT  
800 CENTENNIAL AVENUE  
PISCATAWAY, NJ 08855

EXAMINER

CHEU, CHANGHWA J

ART UNIT

PAPER NUMBER

1641

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/594,187	VAN ALSTINE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	JACOB CHEU	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 18-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/25/2006</u> .   | 6) <input type="checkbox"/> Other: _____                          |

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**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election without traverse of group I, claims 1-17 in the reply filed on 7/15/2008 is acknowledged.
2. Currently, claims 1-17 are under examination. Claims 18-28 are withdrawn from further consideration.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "antibody compound" is not defined in the specification and such term is not commonly used in the art. Please clarify.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:  
A person shall be entitled to a patent unless –  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
5. Claims 1-3, 6, 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenstreich et al. (J. Exp. Med. 1988 Vol. 168, page 1767-1779).

Rosenstreich et al. teach a method of isolating IL-1 target molecules in a liquid samples by at least two chromatography. Rosenstreich et al. teach using an ion-exchange

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chromatography followed by hydrophobic chromatography where Rosenstreich et al. also teach using a non-ionic polyether, i.e. poly(ethylene) glycol, to isolate the target IL-1 (See page 1768 to 1769).

With respect to claims 2-3, the target IL-1 would adsorb unto the chromatography and be eluted by suitable solvent. *supra*.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-3, 5-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gagnon (Purification Tools for Monoclonal Antibodies, 1996, chapter 9, page 155-198; Validated Biosystem Inc.; Applicant's submitted IDS information) in view of Kitajima et al. (US 20030021783) or Haurum et al. (US 20060275766).

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Gagnon et al. teach using affinity chromatography column, ion-exchange chromatograph and hydrophobic chromatography to isolate (separation) and purify target antibody from liquid serum samples. This reference is a tool book and starting with introducing affinity chromatograph to isolate IgG, then on using ion-exchange chromatograph to remove protein A from the previous separation, and lastly disclosing using hydrophobic chromatograph to remove leachate (page 159 to page 182; also page 185 for hydrophobic column). Gagnon also teaches using a non-ionic polyether, e.g. PEG, to contacting the matrix of the column (See page 159, first paragraph; page 177). However, Gagnon does not explicitly teach combining these three chromatography steps together.

Kitajima et al. teach isolation of antibodies by combining suitable affinity chromatography, ion-exchange chromatography and hydrophobic chromatography (See section 0101).

Haurum et al. also teach using combination of affinity chromatography, ion-exchange chromatography and hydrophobic chromatography for isolation antibodies. Haurum et al. indicate that such technique has been frequently been used in the art (Section 0167).

It would have been prima facie obvious to one ordinary skill in the art at the time the invention was made to have motivated Gagnon to use all three chromatography steps for a thorough isolation of antibodies as taught by Kitajima et al or Haurum et al... One ordinary skill in the art would have been motivated to do in order to remove unnecessary mixtures or contaminants from the antibodies by employing all three chromatography.

With respect to claim 2-3, the IgG would adsorb unto the matrix of protein A within the column.

With respect to claims 5-6, it would have been obvious to use the sequence of affinity chromatograph, ion-exchange and hydrophobic chromatograph since Gagnon et al. disclose the same steps.

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With respect to claims 8-9, Gagnon teaches using PEG in the affinity column.

With respect to claim 10, Gagnon teaches using PEG also in ion-exchange chromatography (See page 177).

With respect to claims 11-13, the protein A is used as a ligand to capture antibody (See Gagnon above).

9. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gagnon in view of Kitajima or Haurum et al., as applied to claim 1 above, and further in view of Bander et al. (US 20040120958).

Gagnon, Haurum and Kitajima et al. references have been discussed but no explicit teachings on using consecutive ion-exchange chromatography.

Bander et al. teach using consecutive ion-exchange chromatography for isolation of antibodies (See Section 0374).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Gagnon, Haurum and Kitajima with consecutive ion-exchange chromatography to isolate antibodies because Kitajima or Haurum teaches using suitable ion-exchange chromatography in combination with affinity and hydrophobic columns. Using two consecutive ion-exchange chromatography is for optimization and further purification, and such modification merely requires routine skill in the art.

10. Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gagnon in view of Kitajima or Haurum et al., and further in view of Odink et al. (US 5350687).

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Gagnon, Haurum and Kitajima references have been discussed above and Gagnon teaches immobilizing protein A on the column but Gagnon does not disclose details of the carrier in the chromatography column.

Odink et al. teach using carriers, such as cross-linked polysaccharide extenders, e.g. dextran, as a carriers having protein A ligand immobilized thereon (Col. 6, line 15-60). Odink et al. indicate that using these cross-linked carriers in the affinity chromatography is well-known and requires merely routine skill in the art.

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Gagnon, Haurum and Kitajima with cross-linked extender carrier, such as dextran for protein A in affinity column, as taught by Odink et al. for isolation of antibodies. Such technique is well-known and widely practiced in the art.

### ***Conclusion***

11. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACOB CHEU whose telephone number is (571)272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacob Cheu/

Examiner, Art Unit 1641